

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Antiviral Drugs Advisory Committee (AVDAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
May 10, 2012

AGENDA

The committee will discuss an efficacy supplement for new drug application (NDA) 21-752, TRUVADA® (emtricitabine/tenofovir disoproxil fumarate), submitted by Gilead Sciences, Inc. The supplemental application proposes an indication for Pre-Exposure Prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection.

8:00 a.m.	Call to Order and Introduction of Committee	Judith Feinberg, M.D., FACP, FIDSA Acting Chairperson, AVDAC
	Conflict of Interest Statement	Yvette Waples, Pharm.D. Acting Designated Federal Officer, AVDAC
8:05 a.m.	Opening Remarks	Debra Birnkrant, M.D. Director, Division of Antiviral Products (DAVP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	GUEST SPEAKER PRESENTATION	
	U.S. HIV Epidemiology and Risk	Susan Buchbinder, M.D. Director, HIV Research Section San Francisco Department of Public Health San Francisco, California
8:35 a.m.	CDC PRESENTATION	
	CDC PrEP Studies	Lynn A. Paxton, M.D., M.P.H. Captain, United States Public Health Service Medical Epidemiologist, Epidemiology Branch Division of HIV/AIDS Prevention Center for Disease Control and Prevention (CDC) Atlanta, Georgia
8:55 a.m.	Clarifying Questions from Committee	
9:10 a.m.	SPONSOR PRESENTATIONS	Gilead Sciences, Inc.
	Truvada Overview	Andrew Cheng, M.D., Ph.D. Senior Vice President HIV Therapeutics & Development Operations Gilead Sciences, Inc.

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AGENDA (cont.)

Pre-Exposure Prophylaxis (PrEP) Initiative

Robert M. Grant, M.D., M.P.H.

Senior Investigator, Gladstone Institute of Virology
& Immunology
Professor of Medicine
University of California, San Francisco

Antiretroviral PrEP for HIV-1 Prevention
Among Heterosexual Men and Women: the
Partners PrEP Study

Connie Celum, M.D., M.P.H.

Professor, Departments of Global Health and
Medicine
Adjunct Professor, Department of Epidemiology
Director, International Clinical Research Center
University of Washington

Jared Baeten, M.D., Ph.D.

Associate Professor, Departments of Global Health
and Medicine
Adjunct Associate Professor, Department of
Epidemiology
University of Washington

Truvada for PrEP

Andrew Cheng, M.D., Ph.D.

Closing Comments

John W. Mellors, M.D.

Chief, Division of Infectious Diseases
University of Pittsburgh

10:40 a.m. Clarifying Questions from Committee

10:55 a.m. **BREAK**

11:10 a.m. **NIH PRESENTATION**

VOICE Trial

Jeanna M. Piper, M.D.

Senior Medical Officer, Division of AIDS
National Institute of Allergy and Infectious
Diseases, National Institutes of Health (NIH)
Bethesda, Maryland

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AGENDA (cont.)

11:20 a.m. **FDA PRESENTATIONS**

Truvada: Pre-exposure Prophylaxis (PrEP)
Indication for Prevention of Sexually Acquired
HIV-1

Peter Miele, M.D.
Medical Officer
DAVP, OAP, OND, CDER, FDA

Proposed Risk Evaluation and Mitigation
Strategy (REMS) for Truvada for a Pre-exposure
Prophylaxis (PrEP) Indication for Prevention of
HIV-1 Infection

Carolyn L. Yancey, M.D.
Medical Officer
Division of Risk Management
Office of Medication Error Prevention and Risk
Management
Office of Surveillance and Epidemiology (OSE)
CDER, FDA

12:10 p.m. Clarifying Questions from the Committee

12:40 p.m. **LUNCH**

1:40 p.m. Open Public Hearing

3:40 p.m. **BREAK**

3:55 p.m. Charge to the Committee

Debra Birnkrant, M.D.

Questions to the Committee and Committee
Discussion

6:30 p.m. **ADJOURNMENT**